

REMARKS

Claims 38-56 and 76-168 are pending in the patent application. Claims 87-118, 122, 141 and 160 have been withdrawn without prejudice as a result of the restriction requirement. The Applicants reserve the right to pursue these claims in other patent applications. Claims 38 and 76 have been amended to recite the phrase “wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed.” Claims 119 and 157 have been amended to recite the phrase “the carbon monoxide associated with the raw meat is adapted to be removable.” Claim 138 has been amended to recite the phrase “the carbon monoxide associated with the raw meat is removed.” Support for these amendments may be found at, for example, page 12, lines 2-12 and the examples of the present application. No new matter has been entered. After entry of these amendments, claims 38-56, 76-86, 119-121, 123-140, 142-159, and 161-168 are pending in the patent application.

I. **35 U.S.C. § 103(a) Rejections**

The Applicants are submitting herewith evidence in the form of a 37 C.F.R. §1.132 declaration by one skilled in the art of meat processing using modified atmosphere packaging (Dr. Melvin C. Hunt) (Exhibit 1) to assist in showing the non-obviousness of the invention.

The Applicants are also submitting herewith evidence in the form of a 37 C.F.R. §1.132 declaration by one of the co-inventors Mr. Gary R. DelDuca (“the DelDuca Second Declaration”) (Exhibit 2) to assist in showing the non-obviousness of the invention. The Applicants note that Mr. DelDuca previously submitted a declaration (“the DelDuca First Declaration”)¹ to assist in explaining the invention and showing the non-obviousness of the invention.

¹ The DelDuca First Declaration was filed with the Amendment and Response to Office Action Dated May 7, 2003.

A. A *Prima Facie* Case Has Not Been Presented with Respect to Independent Claims 38, 76, 119, 138 and 157

The present invention is directed to novel methods of manufacturing modified atmosphere packages and modified atmosphere packages. The present invention does not “fix” the color of the meat pigment to red with its use of carbon monoxide (CO), but rather it is believed that the meat pigment would tend to turn brown in a natural time period. *See* page 12, lines 10-12 of the application; Hunt Decl. ¶¶ 7-9; DelDuca Second Decl. ¶¶ 7-9. It is important to prevent the meat color from being “fixed” because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but is beyond the point of microbial soundness. *See* DelDuca Second Decl. ¶ 4.

Amended independent claims 38 and 76 recite, *inter alia*, (a) “a first layer having at least a portion being substantially permeable to oxygen”; (b) “a second layer being substantially impermeable to oxygen”; (c) a low oxygen environment that includes from about 0.1 to about 0.8 vol% carbon monoxide (CO); and (d) “wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed.”

Amended independent claims 119 and 157 recite, *inter alia*, (a) “a first layer having at least a portion being substantially permeable to oxygen”; (b) “a second layer being substantially impermeable to oxygen”; (c) a low oxygen environment that includes from about 0.1 to about 0.8 vol% carbon monoxide (CO); and (d) “the carbon monoxide associated with the raw meat is adapted to be removable.”

Amended independent claim 138 recites, *inter alia*, (a) “a first layer having at least a portion being substantially permeable to oxygen”; (b) “a second layer being substantially impermeable to oxygen”; (c) a low oxygen environment that includes from about 0.1 to about 0.8 vol% carbon monoxide (CO); and (d) “the carbon monoxide associated with the raw meat is removed.”

The applied references in the Office Action do not teach or suggest such limitations that are recited in independent claims 38, 76, 119, 138 and 157.

As acknowledged in the Office Action at page 3, U.S. Patent No. 5,686,127 to Stockley (“Stockley”) is silent in teaching or suggesting the use of CO. The other applied reference (U.S. Patent No. 4,522,835 to Woodruff (“Woodruff”)) does not disclose a packaging system having

(a) “a first layer having at least a portion being substantially permeable to oxygen”; (b) “a second layer being substantially impermeable to oxygen” as recited in independent claims 38, 76, 119, 138 and 157. In response to the deficiencies of these applied references, the Office Action stated the following:

It would have been obvious to modify the carbon dioxide atmosphere taught by Stockley et al. [Stockley] and include anywhere from 0.1-0.8% carbon monoxide in addition to the carbon dioxide as recited in claims [], since Woodruff et al. [Woodruff] teach carbon monoxide at these levels in addition to at least 10% carbon dioxide will provide a desirable red color of fresh meat for meat stored with a low/no oxygen modified atmosphere.

Office Action at page 4.

i. No Motivation to Combine the References

This passage in the Office Action, however, ignores the understanding of those of ordinary skill in the art that CO fixes the color of the meat and, thus, there would be no motivation to one of ordinary skill in the art for using CO in a modified atmosphere such as disclosed in Woodruff with a meat packaging system such as disclosed in Stockley. The problems of fixing meat color with CO, which can mask spoilage, are clearly known to those of ordinary skill in the art. *See, e.g.*, Hunt Decl. ¶ 6; DelDuca Second Decl. ¶ 4. The problem of fixing meat color with CO was described in a previously applied reference in the Office Action dated May 7, 2003 to Sorheim et al.² Furthermore, the United States Food and Drug Administration (FDA) has believed that the meat pigment color would be fixed using CO.³ Thus, the alleged “good” color (*i.e.*, red color of fresh meat) disclosed in Woodruff is not a desirable attribute when the meat pigment remains such a color past its microbial soundness.

² The applied reference was “The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide” from *Meat Science* to Sorheim et al. (“Sorheim”). In particular, Sorheim disclosed that its meat packaging systems with a modified atmosphere of “0.4% CO/60% CO₂/40% N₂ had a bright stable red colour that lasted beyond the time of spoilage.” Abstract of Sorheim.

³ Exhibit 3 (In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data “to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated” and that the FDA has a question “concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color.”); see also Hunt Decl. ¶ 6

Thus, there is simply no motivation to combine Stockley and Woodruff in an attempt to address the problems solved by the present invention and to read on the pending claims.

The other applied reference (U.S. Patent No. 5,629,060 to Garwood (“Garwood”)) has the same deficiencies as Stockley. Specifically, Garwood does not disclose the use of CO in its respective packaging system, let alone the claimed amount of CO recited in the independent claims.

Thus, there is no motivation to combine the references of Stockley, Woodruff, Garwood, or any combination thereof in an attempt to read on the pending claims. The mere fact that references can be combined together or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). “When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.” *Rouffet*, 149 F.3d at 1355, 47 U.S.P.Q.2d at 1456, (citing *In re Geiger*, 815 F.2d 686, 688, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987)). Evidence of a suggestion, teaching, or motivation to combine “must be clear and particular.” See *Ex parte Maruyama*, 2001 WL 1918556, *3 (Bd. Pat. App. & Inter. 2001), (citing *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998)).

Obviousness cannot “be established using hindsight or in view of the teachings or suggestions of the invention.” *Ex parte Maguire* (Appendix 9), 2002 WL 1801466, *4 (Bd. Pat. App. & Inter. 2002), (quoting *Para-Ordnance Mfg. Inc. v. SGS Imps. Int'l Inc.*, 73 F.3d 1085, 1087, 37 U.S.P.Q.2d 1237, 1239 (Fed. Cir. 1995), cert. denied, 519 U.S. 822 (1996)). In other words, the knowledge to combine “can not come from the applicant’s invention itself.” *In re Oetiker*, 977 F.2d 1443, 1447, 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992).

Thus, the Applicants believe that a *prima facie* case has not been presented with Stockley, Woodruff, Garwood, or any combination thereof.

B. Evidence of Non-Obviousness of Independent Claims 38, 76, 119, 138 and 157

Assuming, *arguendo*, that a *prima facie* case has been presented (which Applicants believe is not the case), the Applicants are submitting evidence of non-obviousness in the form of

two declarations – the Hunt Declaration (Exhibit 1) and the DelDuca Second Declaration (Exhibit 2) to assist in showing the non-obviousness of the invention.

i. CO Not Allowed with Fresh Meat in the United States Since At Least 1962

CO had not been allowed to be used with fresh meat in the United States for about 40 years. *See Exhibit 3 (1962 Whirlpool letter); DelDuca Second Decl. ¶ 4.* The concern of the FDA is believed to be that CO fixes the fresh meat color to a degree that allows the retailer to sell meat that looks good (a bright red color), but is beyond the point of microbial soundness. *Id.*

ii. CO Now Allowed In Pactiv's Novel Approaches

After about 40 years of not allowing CO to be used with fresh meats in the United States, the Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concerns of “fixing” the meat color. *Id.*

a. One Novel Pactiv Approach⁴

One of the novel approaches invented by the Applicants that avoids the concerns of fixing the color of the meat pigment involved using a specific MAP system that was presented in a GRAS notice (“Pactiv’s improved ActiveTech® meat packaging system”). Pactiv’s improved ActiveTech® meat packaging system included meats being placed in polystyrene trays and covered with oxygen-permeable, polyvinyl chloride (“PVC”) overwraps. DelDuca Second Decl. ¶ 5. The wrapped trays of meat are then placed in an outer barrier bag. *Id.* Ambient air is removed and replaced with a blend of 0.4% CO, 30% carbon dioxide, and the balance being nitrogen. *Id.*

Dr. Hunt, who has extensive experience in the processing of meat using modified atmosphere packaging, stated that “[t]he results of the testing [of the Pactiv’s improved ActiveTech® meat packaging system] were surprising to me because it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red.” Hunt Decl. ¶ 6. Pactiv’s improved ActiveTech® meat

⁴ This novel approach is the subject of another patent application.

packaging system using 0.4 vol.%, however, did not fix the color of the meat pigment as expected and Dr. Hunt stated that “[t]his was a novel result and was not at all obvious due to the current and long standing thought that meat exposed to CO would develop a color that would mask spoilage.” *Id.*

The FDA stated that it had no questions regarding Pactiv’s conclusion about Pactiv’s improved ActiveTech® meat packaging system using 0.4% CO being GRAS because of the evidence presented by Pactiv in its GRAS notice. DelDuca Second Decl. ¶ 6. This FDA review allows Pactiv to use CO with fresh meat in its application. *Id.* It is believed to be the first system to overcome the prohibition of CO with fresh meat in the United States in the last 40 years. *Id.*

b. Another Novel Pactiv Approach

Besides Pactiv’s improved ActiveTech® meat packaging system, the Applicants invented other novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoid the concerns of “fixing” the meat color. Some of these other novel approaches include low oxygen environment, meat packaging systems having (a) a first layer being a substantially permeable layer, (b) a second layer being a substantially impermeable layer, and (c) a gas mixture including 0.4 vol.% CO.

An example of a low oxygen environment, meat packaging system that uses (a) a first layer being a substantially permeable layer and (b) a second layer being a substantially impermeable layer is a “peelable” system. *Id.* at ¶ 8. A peelable system typically places a piece of meat on a tray in which the tray is sealed by a first layer that is substantially permeable and a second layer that is substantially impermeable. *Id.* The first layer is located closest to the meat, while the second layer is located farthest from the meat. *Id.* The second layer is then peeled apart from the first layer such that the gas mixture contained within the package exchanges with the atmosphere through the substantially permeable first layer. *Id.*

The process of manufacturing the above-described peelable system is one example of a process that would be covered by independent claims 38, 119 and 138 of the present application. *See id.* at 9. The above-described peelable system is one example of modified atmosphere packaging that would be covered by independent claims 76 and 157 of the present application. *Id.*

It is believed that using such peelable systems with 0.4 vol.% CO would not fix the color of the meat pigment to red. DelDuca Second Decl. ¶ 9; Hunt Decl. ¶¶ 7-9. Rather, the meat pigment would turn brown (discolored) in a pattern typical of retail meat in display but packaged in a standard supermarket format (foam tray and PVC overwrap). DelDuca Second Decl. ¶ 9; Hunt Decl. ¶ 9.

Cryovac makes such a peelable system using 0.4 vol.% CO under the name Darfresh®. DelDuca Second Decl. ¶ 11. Cryovac in its GRAS notice represented that the Cryovac package “allow[s] the meat pigment color to change over time as though it has not been exposed to CO.” *See* DelDuca Second Decl. ¶ 11 and Exhibit A attached thereto. As a result, the “FDA concluded that Cryovac’s MAP system fell within the scope of GRAS Notice No. GRN 00083 [which is directed to Pactiv’s improved ActiveTech® meat packaging system].” *Id.* Thus, both Cryovac and the FDA believe that such a peelable system using 0.4 vol.% CO would not fix the color of the meat pigment to red.

Dr. Hunt also stated that he believed “that the surprising results obtained in the testing of Pactiv’s ActiveTech® meat packaging system using 0.4 vol.% CO would be equally applicable” to methods such as the peelable system described above. Hunt Decl. ¶ 7.

Thus, a problem of fixing meat color with CO that was recognized for at least the last 40 years was overcome by various inventive embodiments/methods of the Applicants including (a) Pactiv’s improved ActiveTech® meat packaging system and process of manufacturing the same; and (b) a peelable meat packaging system described above and process of manufacturing the same, which is an example of a system and a process that would be covered by the independent claims of the present application. Additionally, such results were surprising to one skilled in the art (Dr. Hunt) in that they did not fix the color of the meat pigment to red.

iii. Pactiv’s Novel Meat Packaging Systems and Methods of Manufacturing the Same Addressed a Long-Felt Need

The Federal Circuit has stated that if an invention unexpectedly solved longstanding problems, it supports the conclusion of nonobviousness. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1382 (Fed. Cir 1986); *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999).

Pactiv's novel meat packaging systems and methods of manufacturing the same are examples of systems and processes that addressed such a long-felt need. More specifically, both (a) Pactiv's improved ActiveTech® meat packaging system and (b) a peelable meat packaging system described above and process of the same, which is an example of a system and a process that would be covered by independent claims of the present application, addressed such a long-felt need in the meat-packaging industry. "Prior to Pactiv's novel meat packaging approaches using 0.4 vol.% CO, there was a need in the industry to provide a solution that: (a) reduced the seasoning period (the critical time meat is exposed to low partial pressures of oxygen, which can seriously damage the pigment chemistry); (b) formed consistently a normal bloomed color with meats whose pigment is sensitive to metmyoglobin formation; and (c) avoided the fixing of too stable of a meat color, which can be unsafe and potentially dangerous, if the color stability was greater than the shelf life (microbial soundness) of the product." *See* Hunt Decl. ¶¶ 10, 11. "Such a solution was especially desirable for a centralized packaging facility where the meat would be shipped to distant locations." *See id.* Pactiv's novel meat packaging systems using 0.4 vol.% CO were new and novel approaches that addressed these technological needs." *See id.*

Thus, since Pactiv's novel meat packaging systems using 0.4 vol.% CO surprisingly addressed a long-felt need, this is further evidence that the independent claims of the present application are not obvious over the applied references.

Therefore, in addition to the applied references not presenting a *prima facie* case, the Applicants also believe that the present invention is allowable because of the compelling evidence of non-obviousness. Therefore, independent claims 38, 76, 119, 138 and 157 are not obvious in view of Stockley, Woodruff, Garwood, or any combination thereof and, thus, should be in a condition for allowance.

C. Dependent Claims 39-56, 77-86, 120, 121, 123-137, 139, 140, 142-157, 159, and 161-168

Dependent claims 39-56, 77-86, 120, 121, 123-137, 139, 140, 142-157, 159, and 161-168, which depend directly or indirectly on independent claim 38, 76, 119, 138 and 157 are not obvious in view of Stockley, Woodruff, Garwood, or any combination thereof for at least the same reasons discussed with respect to claims 38, 76, 119, 138 and 157. Thus, claims 39-56, 77-86, 120, 121, 123-137, 139, 140, 142-157, 159, and 161-168 should be in a condition for allowance.

D. Conclusion

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. The Applicants are including a one-month extension fee and it is believed that no other fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Jenkens & Gilchrist, P.C. Deposit Account No. 10-0447, Order No. 47097-01106USC1.

Respectfully submitted,

October 14, 2004
Date


John C. Gatz
Reg. No. 41,774
JENKENS & GILCHRIST, P.C.
225 West Washington Street, Suite 2600
Chicago, IL 60606-3418
(312) 425-3900

Attorneys for Applicants